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EXAMINER	
KIM, JENNIFER M	

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1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,357	BABUL, NAJIB	
	Examiner	Art Unit	
	JENNIFER M. KIM	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,20-31 and 41-55* is/are pending in the application.

4a) Of the above claim(s) *14 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,20-31,41 and 43-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/19/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of species election of opioids namely, **morphine** is acknowledged. Accordingly, claims 1-13, 17, 20-31, 41 and 43-55 have been examined only to the extent of Applicants' elected species (morphine). Claims 14 and 42 have been withdrawn from consideration since it is non-elected invention.

Action Summary

The rejection of claims 1-13, 17 and 20-31 drawn to "prevention" under 35 U.S.C. 112, first paragraph, is being **maintained** for the reasons stated in the previous Office Action.

The rejection of claims 1-13, 17 and 20-31 drawn to "an opioid" and "adrenergic agonists" under 35 U.S.C. 112, first paragraph, is being **maintained** for the reasons stated in the previous Office Action.

The rejection of claims 1-13, 17, 20-24 and 28-31 under 35 U.S.C. 103(a) as being unpatentable over Breton et al. (U.S.Patent No. 5,958,432) and Naftchi et al. (1981) is being **maintained** for the reasons stated in the previous Office Action. However, the rejection is modified in this Office Action to include the newly added claims 41 and 43-55.

The rejection of claims 25, 26 and 27 under 35 U.S.C. 103(a) as being unpatentable over Breton et al. (U.S.Patent No. 5,958,432) and Naftchi et al. (1981) as applied to claims 1-14, 17, 20-25 and 28-31, and further in view of Malmqvist-Granlund et al. (U.S.Patent No. 5,178,868) is being **maintained** for the reasons stated in the previous Office Action.

The rejection of claims 1-13, 17 and 20-31 under 35 U.S.C. 103(a) as being unpatentable over Brochet et al. (1986) is being **maintained** for the reasons stated in the previous Office Action. However, the rejection is modified in this Office Action to include the newly added claims 41 and 43-55.

Response to Arguments

Applicant's arguments filed May 19, 2008 have been fully considered but they are not persuasive. With regard to 35 U.S.C. 112, first paragraph "prevention of pain", Applicant argues that the mouse in the working example in the instant specification, was subjected to the tail-flick test after administration of albuterol alone, morphine alone and then administration of both albuterol and morphine. And that this test is as applicable to the prevention of pain, as it is to the treatment of pain because the mouse is not in pain before administration of the active agents. This is not found to be persuasive because the examples in the specification is enabling for the treatment or the reduction of pain by administration of the active agents before the induction of pain, it does not enable for the prevention. The enhanced analgesic effect of morphine in the presence of albuterol

would be only applicable for the treatment of pain, rather than prevention. The instant claims are directed to a method of preventing pain that is difficult to even treat, and it is especially true of most cancer pain. It is well known in the art that in some types of advanced cancers, the pain cannot be alleviated by any known method. Therefore, it is highly speculative that the pain can be actually prevented. It is noted that no data has been prevented to establish that instant compounds would act in the manner claimed as they relate to the prevention of pain in general. The Examiner has provided the factual evidence (Shantha (U.S.Patent No. 5,735,817) and Davar (U.S.Patent No. 6,6673,832 B1) to show why it is highly unlikely to establish the instant claims drawn to prevention of pain. The examples in the instant specification is all directed to the reduction rather than prevention of the painful conditions.

With regard to 35 U.S.C. 112, first paragraph written description rejection beyond morphine and albuterol, Applicant argues that that enablement of morphine enables the entire class of opioids because the synergistic effect with combination treatment of morphine and albuterol is disclosed in the specification. This is not found to be persuasive because the specification has been carefully considered and reviewed. The "synergistic" combination testing in the examples is limited to data for the specific combination (morphine and albuterol). Thus, the testing is very specific whereas none of the instant claims are so limited. The guidance given by the specification as to how one would actually practice the invention of preventing pain with any opioids and any beta-adrenergic agonist is minimal (only those specific combination). Therefore, a method of treating or preventing pain comprising administering to a subject in need of

pain treatment or pain prevention **(a) opioids and (b) beta adrenergic agonists providing enhanced effect** is not considered to be enabled by the instant specification. It is noted that the "evidence" of alleged synergisim is not commensurate in scope with the breadth of the claims. It is well established that a showing of unexpected results generally must be commensurate in scope with the breadth of the claims sought to be patented. See, inter alia, (1) In re Greenfield, 571 F.2d 1185, 1189, 197 USPQ 227, 230 (CCPA 1978) (showing of unexpected results must be commensurate in scope with breadth of claim); (2) In re Kulling, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990) (same); and (3) In re Lindner, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972) (same).

With regard to 35 U.S.C. 103 (a) rejection over Breton et al. (U.S.Patent No. 5,958,432) and Naftchi et al., Applicant takes position that the cited prior art (Breton et al. and Naftchi et al.) does not teach or suggest that the combination of one or more opioids and one or more beta adrenergic agonist, therefore, the combination of these references cannot render the presently claimed invention obvious. **This is not found to be persuasive because** Breton et al. teach that beta-adrenergic agonist including salbutamol, isoproterenol, CGP1217, nylidrin, salmeterol, fenoterol, terbutaline or pirbuterol are substance P antagonists, which are involved in the transmission of pain. Naftchi et al. suggest that morphine analgesic is due to inhibition of intraneuronal substance P release in regions. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). One of ordinary skill in the art would have combined the

antischizophrenic agents by known methods and that in combination, each element merely would have performed the same antischizophrenic activity as it did separately. The convenience of putting the compounds having the same analgesic activity of the beta-adrenergic agonist and morphine together in one dosage form, though perhaps a matter of great convenience does not produce a "new" or "different" function and to those skilled in the art, the use of the old elements in combination would have been obvious. With regard to 35 U.S.C. 103 (a) rejection over Breton et al. (U.S.Patent No. 5,958,432) and Naftchi et al. in further in view of Malmqvist-Granlund et al., Applicants argue that Malmqvist-Granlund et al. is only directed to a very specific oral formulation, therefore, it does not teach or suggest the combination of these different class of drugs and that the beta adrenergic agonist might enhance the effect of the opioids. This is not found to be persuasive because Breton et al. teach that beta-adrenergic agonist including salbutamol, isoproterenol, CGP1217, nylidrin, salmeterol, fenoterol, terbutaline or pirbuterol are substance P antagonists, which are involved in the transmission of pain. Naftchi et al. suggest that morphine analgesic is due to inhibition of intraneuronal substance P release in regions. Therefore, the employment of combinations comprising opioids and beta adrenergic agonist to treat pain would have been obvious because all the components are well known individually for treating pain. It would be expected that the combination of components would treat painful conditions as well. The motivation for combining the components flows from their individually known common utility.

With regard to 35 U.S.C. 103 (a) rejection over Brochet et al., Applicant does not disagree that the Brochet et al. teaches the beta adrenergic agonists, isoproterenol,

albuterol (salbutamol) and clenbuterol produce a modest antinociceptive in the rat hot plat model when given intraperitoneally, and this result is consistent with the data presented by Applicants showing an antinociceptive effect of albuterol, however, Applicant argues that the Brochet et al. does not teach or suggest combining beta adrenergic agonists with any other active, agent to obtain additive effect to provide analgesic dose sparing effects or to ameliorate analgesic side effects. This is not found to be persuasive because Brochet et al. teach that the antinociceptive activity of beta-adrenoreceptor agonist is well known in the art. One of ordinary skill in the art would have combined the beta-adrenoreceptor agonist together with other well known analgesic agents (e.g. opioids) by known methods and that in combination, each element merely would have performed the same antinociceptive or analgesic activity as it did separately. The convenience of putting the compounds having the same antischizophrenic activity of rimonabant and risperidone together in one dosage form, though perhaps a matter of great convenience does not produce a "new" or "different" function and to those skilled in the art, the use of the old elements in combination would have been obvious.

Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Objections

Claims 49 and 50 are objected to because of the following informalities: The terms “Buprenorphine, Butorphanol, Codeine, Dezocine, Diamophine,

Hydromorphone.. ...**Morphine**..." etc.. are capitalized, leading to uncertainty regarding whether the terms are a trade names. It is suggested to use lower case throughout.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-13, 20-31, 41 and 43-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treating pain", does not reasonably provide enablement for the "preventing pain". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method of treating or preventing pain comprising administering to a subject in need of pain treatment or pain prevention (a) opioids and (b) beta adrenergic agonist. The nature of the invention is complex in that it encompasses the actual prevention of pain (e.g. cancer pain) such that the subject treated with above compounds does not contract pain.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass preventing pain in humans which has potentially many different causes (i.e. many different medical disorders, drug side-effects (chemotherapeutic agents, radiation or surgery, etc..). Each of which may or may not be addressed by the administration of the claimed compounds.

Guidance of the Specification: The guidance given by the specification as to how one would administered the claimed compounds to a subject in order to actually prevent pain is minimal. All of the guidance provided by the specification is directed towards treatment rather than prevention of pain.

Working Examples: All of the working examples provided by the specification are directed toward the treatment rather than prevention of pain.

State of the Art: While the state of the art is relatively high with regard to treatment of painful disorder (i.e. cancer pain), the state of the art with regard to prevention of such disorders is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein a compound

similar to the claimed compounds was administered to a subject to prevent development of pain. State of the Art, Shantha (U.S. Patent No. 5,735,817) teaches that painful conditions, which affect our body, are **difficult to treat**, and it is especially true of most cancer pain. In some types of advanced cancers, the pain **cannot be alleviated** by any known method. Shantha also teaches that even with **hundreds of milligrams of morphine** administration, the **pain could not be relieved**. (column 1, lines 1-30). State of the Art, Davar (U.S.Patent No. 6,6673,832 B1) also teaches that the **cancer pain is often debilitating and difficult to treat**, especially in patients with advanced disease and the pain treatment often requires very large doses of either systemic or intraspinal opioids, often an insufficient pain treatment that produced undesirable side-effect. (column 1, line 62- column 2, line 10). Therefore, it is highly speculative that the active compounds would actually "prevent" the pain condition that is considered to be difficult in the treatment process.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual prevention of pain in a human subject with the claimed compounds makes practicing the claimed invention unpredictable in terms of prevention of pain.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the

claimed compounds and test the combination in the model system to determine whether or not the combination is effective for prevention of pain. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard prevention of pain with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding prevention of pain with any compound, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to prevent the development of pain in a subject by administration of one of the claimed compounds.

Therefore, a method of treating or **preventing** pain comprising administering to a subject in need of pain treatment or pain **prevention** (a) opioids and (b) beta adrenergic agonist is not considered to be enabled by the instant specification.

4. Claims 1-13, 20-31, 41 and 43-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treating pain comprising administering the specific opioid (i.e. morphine) and the specific beta

adrenergic agonist (i.e. albuterol) ", does not reasonably provide enablement for the "treating pain administering opioids and beta adrenergic agonists". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. All of the rejected claims are drawn to a method of treating or preventing pain comprising administering to a subject in need of pain treatment or pain prevention **(a) opioids and (b) beta adrenergic agonists providing enhanced effect**. The nature of the invention is complex in that it encompasses the various opioids and beta adrenergic agonists that are structurally different such that the subject treated with above compounds enhancing analgesic effect in pain treatment.

The guidance given by the specification as to how one would actually practice the invention of preventing pain with **any opioid and any beta-adrenergic agonist** is minimal. All of the guidance of the working examples are directed to the employment of specific opioid (morphine) and the specific beta-adrenergic agonist (albuterol). The specification teaches how to treat pain with the specific combination of the active agents (albuterol and morphine) in a subject however, there are no working examples, prophetic or otherwise in the specification how to actually treat pain with the enhanced effect with all of the claimed opioids and beta-adrenergic agonists. The state of the art with regard to determining the enhanced analgesic effect of the combination of any opioids and any beta-adrenergic agonists in a subject is not predictable. Given the complex nature of the invention, which involves enhanced analgesic effect with any opioids and any beta-adrenergic agonists in the breadth of the claim, the complete lack

of guidance from the specification regarding how to interpret the data generated a single combination, minimal of working example as such, the uncertainty of whether the current state of the art regarding the use of such formulations would actually result in enhanced analgesic effect with any combination of opioids and beta-adrenergic agonists. It would take undue, unpredictable experimentation to practice applicant's invention to treat pain with combination of opioids and beta-adrenergic agonist produces enhanced analgesic effect. Therefore, a method of treating or preventing pain comprising administering to a subject in need of pain treatment or pain prevention **(a) opioids and (b) beta adrenergic agonists providing enhanced effect** is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13, 20-24, 28-31, 41 and 43-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breton et al. (U.S.Patent No. 5,958,432) and Naftchi et al. (1981).

Breton et al. teach that beta-adrenergic agonist including salbutamol, isoproterenol, CGP1217, nylidrin, salmeterol, fenoterol, terbutaline or pirbuterol are

substance P antagonists, which are involved in the transmission of pain. (column 2, lines 28-31, and column 1, lines 45-50, column 3, lines 9-15).

Naftchi et al. suggest that morphine analgesic is due to inhibition of intraneuronal substance P release in regions. (abstract).

The claims differ from the cited references in claiming combination of opioids, and beta-adrenergic agonist, to treat pain. To employ combinations of opioids and beta adrenergic agonist to treat pain would have been obvious because all the components are well known individually for treating pain. It would be expected that the combination of components would treat painful conditions as well. The motivation for combining the components flows from their individually known common utility.

As stated in In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

> It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art.

Therefore, it would have been prima facie obvious to combine opioid and beta-adrenergic agonist conjointly in a formulation to treat pain. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

The amounts of active agents to be used, the pharmaceutical forms, e.g., tablets, etc stereoisomers or enantiomers..etc..; mode of administration, flavors, surfactant are

all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration.

Claims 25, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breton et al. (U.S.Patent No. 5,958,432) and Naftchi et al. (1981) as applied to claims 1-13, 20-24, 28-31, 41 and 43-55 above, and further in view of Malmqvist-Granlund et al. (U.S.Patent No. 5,178,868).

The teachings of Breton et al. and Naftchi et al. as applied as before.

Breton et al. and Naftchi et al do not teach the oral administration. Malmqvist-Granlund et al. teach that morphine and salbutamol (also known as albuterol) can be formulated as an oral formulation.

It would have been obvious to one of ordinary skill in the art to modified the obvious combination of opioid (morphine) and salbutamol as modified by Breton and Naftchi et al. in a single oral formulation because each of the active agents are suitable for the oral administration as taught by Malmqvist-Granlund et al. One would have been motivated to make such a modification in order to provide most convenient analgesic therapy by oral administration. There is a reasonable expectation of orally administering the obvious combination modified by Breton and Naftchi et al. because each of the active agents are suitable in oral dosage form as taught by Malmqvist-Granlund et al.

Claims 1-13, 20-24, 28-31, 41 and 43-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brochet et al. (1986).

Brochet et al. teach antinociceptive activity of beta-adrenoreceptor agonists including isoproterenol, clenbuterol and salbutamol (also known as albuterol). (title, abstract, under discussion. Brochet et al. teach that these agents exerted an antinociceptive activity on the hot plate test in mice.

Brochet et al. lack opioids, amounts of salbutamol, the oral administration and mechanisms of action set forth in claims 5-8 and 11-13.

It would have been obvious to one of ordinary skill in the art to modify the teaching of Brochet et al. and incorporate opioids for the treatment of pain because beta-adrenoreceptors such as albuterol is well known by Brochet et al. for having antinociceptive effect and because it is well within the knowledge of one of ordinary skill in the art to combine another analgesic compound such as opioids to achieve at least an additive effect.

As stated in In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

> It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art.

Therefore, it would have been prima facie obvious to combine opioid and beta-adrenergic agonist conjointly in a formulation to treat pain. Further, no unobviousness

is seen in the effective amounts and dosage formulation claimed because once the usefulness of a compound is known to treat a condition, it is within the skill of the artisan to determine the optimum ratio and suitable dosage forms for an individual patient being treated. Further, the mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the obvious method of Brochet et al. to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. An explanation of why that effect occurs does not make unobvious the treatment of the conditions encompassed by the claims.

The amounts of active agents to be used, the pharmaceutical forms, e.g., tablets, etc stereoisomers or enantiomers..etc..; mode of administration, flavors, surfactant are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1617

Jmk
December 12, 2008